REMARKS/ARGUMENTS

Claims 1 through 32 are pending in this application. In the Office Action of November 17, 2005, the Examiner (1) imposed a Restriction Requirement between Invention I, claims 1-21, and Invention II, claims 22-32, (2) rejected claims 22, 24, and 28 under 35 U.S.C. 102(e) as being anticipated by Paton, et al., US 6562037, (3) rejected claims 23, and 25 – 27 under 35 U.S.C. 103(a) as being unpatentable over Paton, et al., and (4) allowed claims 29 – 32.

In response, Applicant has elected Invention II, amended the specification to reflect the current status of the parent application, cancelled claims 1-21, and amended independent claims 22, 24, and 28 to clarify that the electrical stimulation in those claims utilize three or more electrodes. No new matter is added by these amendments, and entry of these amendments is requested. Applicant now believes that the application is in condition for allowance.

RESPONSE TO RESTRICTION REQUIREMENT

Applicant elects without traverse to prosecute the invention of Group II, claims 22-32. Claims 1-21 have been cancelled. Applicant notes that claims 1-21 were prosecuted in the parent Application No. 10/506,911, and a Notice of Allowance has issued in that case.

PENDING INFORMATION DICLOSURE STATEMENTS

Applicant notes that an Information Disclosure Statement was mailed on November 4, 2005, with a properly executed Certificate of Mailing, disclosing Gamble, US 5,161,530. As this was mailed with a Certificate of Mailing before the mailing of the pending Office Action, it was timely under 37 CFR 1.97(b) without payment of any additional fee or statement, and therefore consideration of the IDS is earnestly requested. An additional copy of the IDS is enclosed for the Examiner's convenience.

Applicant also notes that although the Examiner signed the appropriate forms, there

is no examiner's initials next to (1) the Petrofsky et al. reference on line B1 of the Form PTO-1449 considered on 11/14/05, or (2) the Mertz et al. reference on line D1, of the Form PTO-1449 considered on 11/14/05. Additional copies of those forms are also attached. Indication that those two references were considered is earnestly requested.

REJECTION UNDER 35 U.S.C. 102

The Examiner has rejected claims 22, 24, and 28 under 35 U.S.C. 102(e) as being anticipated by Paton, et al., US 6562037. Paton et al, teaches bonding of incisions through tissue albumen denaturation by heating with either a pair of electrodes, or with forceps. If two edges of an incision are connected and heated, the entanglement of albumen molecules result in their bonding. Higher temperatures accelerate this process, but at temperatures exceeding 100 degrees C, the tissue dehydrates, resulting in an increase in electrical resistance, which leads to further temperature rise and charring. (c.1, 34-47.)

In other words, Paton et al teach that an increase in electrical resistance between a pair of electrodes signals the onset of tissue damage due to exceeding the recommended heating limit:

> "Heat is generated by current flow through tissue due to its resistance. Therefore, resistance is used below when the invention is explained in terms of heart due to current flow." (c. 5, 52-54)
>
> "Tissue between electrodes 11 is heated because of heat generated by electric current flowing through the tissue due to the electric resistance of the tissue in zone 7." (c.5, l. 66- c. 6, l. 1)
>
> "When the ratio Z/Z_{OI} reaches a preset value, further heating is stopped by breaking the current flow, e.g., at time t_I. For the next bonding process on another type of tissue,

impedance curve Z_2 is processed in the same way with the result that current flow is stopped at time t_2." (c.14, ll. 57-62)

"Current cutoff to stop the tissue heating is achieved by the control system in response to the relative value of tissue impedance Z/Z_O, as explained above." (c. 15 15-17).

It should be noted that Paton et al. do not teach using more than two electrodes (or forceps) at any given time. There would be no need for more than two electrodes in the bonding process, as the tissue is clamped between the electrodes (Figs. 1-5, and 9), or gripped by forceps (Figs. 16, 18).

On the other hand, Applicant teaches the correlation of electrical resistance, as measured by tissue impedance in any given area of the wound, with healing of wounds, using three or more electrodes. This permits the ability to detect the optimal current to apply into each area of the wound, and allows division of the wound into healing sectors, with optimized healing by varying the currents in different areas of a wound:

"With feedback from the wound as to the degree of healing, information can be provided to a computer, which can then make a decision as to which currents to apply to the wound at what time, and in which areas of the wound to optimize healing in different segments of the wound. The operation can also be done manually, or in conjunction with a computer. In other words, if it is determined that one portion of the wound is healing very slowly, and there is excessive bleeding, a positive current may be applied, whereas in the other areas of the same wound the operator (including automatic operation by a computer) may switch to a negative current to optimize healing in these areas." (emphasis added)

Applicant teaches that there is current generation within a healing wound, which varies by area within the wound:

> "It must be determined which areas of the wound are healing and which are not. This can be accomplished by using tissue voltages and/or tissue impedance. Tissues generate a voltage as mentioned above, when there is a wound. That voltage, which goes very positive at the early stages of the wound, exponentially decays back to only a few millivolts after the wound is healed. Therefore, the fresher the wound is, or the more unhealed the wound is, the higher the electrical voltage being generated in that area of the wound." (emphasis added)

Tissue impedance in an area can then be used as a metric for current, which may then be correlated to a stage of healing in portions of the wound:

> "Tissue impedance is complimentary to current generation. If current is being generated by a portion of the wound, then impedance would be high, since impedance is the resistance to the movement of an electric current. If the tissue generates a current, then the current developed by two electrodes will be opposed by the current generation in the wound. In other words, impedance across a wound will vary as a function of the healing process. These measures of impedance around the wound then would provide information as to the degree of healing of the wound. After impedance is measured across any two electrodes, stimulation current (either positive, negative or alternating) as taught above, will be applied through that electrode pair at the appropriate amplitude to optimize wound healing."

(emphasis added)

The use of electrical stimulation utilizing three or more electrodes, in combination with feedback, therefore achieves significant advantage over the prior art, and is not taught or fairly suggested by Paton et al. Accordingly, independent claims 22, 24, and 28 have been amended to clarify the invention, and are now in condition for allowance.

REJECTION UNDER 35 U.S.C. 103

Dependent claims 23 and 25-27 have been rejected under section 103 as being unpatentable over Paton et al.

Claim 23 provides:

> 23. The method of claim 22, where the electrical stimulation is an AC sine wave with about 250 microsecond pulse width and current of about -10 ma when the impedance is between about 3.7 to about 4.1 ohms per cm of tissue, and the electrical stimulation is an AC sine wave with about 250 microsecond pulse width and current of about -5 ma when the impedance is between about 4.8 and about 5.1 ohms per cm of tissue.

Claims 26 and 27 provide:

> 26. The method of claim 24, where the electrical stimulation comprises a sine wave having between about 220 microsecond and about 250 microsecond pulse width.
>
> 27. The method of claim 24, where the electrical stimulation comprises a sine wave having between 100 microsecond and 1000 microsecond pulse width.

Respectfully, Paton et al. neither teach nor fairly suggest that wound healing can occur with the described ranges of electrical stimulation. These ranges are neither mentioned nor suggested by Paton et al. Note also that Paton et al. teach electrical

stimulation for an entirely different purpose: albumen denaturation. While it may be obvious to one having ordinary skill in the art to have altered the stimulation patterns, it would not have been obvious to have used these ranges of electrical stimulation, and it certainly would not have been something found in Paton et al.

Further, these dependent claims, and dependent claim 25, are dependent upon an allowable independent claim, and should therefore be allowed.

ALLOWED SUBJECT MATTER

Applicant gratefully acknowledges the allowance of claims 29 – 32.

CONCLUSION

For the reasons stated above, and subject to consideration of the outstanding IDS, Applicant respectfully believes that all pending claims, claims 21- 32, are in condition for allowance and such action is earnestly solicited. If, however, there remain any issues that can be resolved by telephone with the Applicant's representative, the Examiner is encouraged to contact the undersigned directly.

No fee is believed due in connection with this communication. If, however, any fee is owed, the Commissioner is hereby authorized to charge payment of the fee associated with this communication to Deposit Account No. 19-2090.

Respectfully submitted,

SHELDON & MAK PC

Date: February 6, 2006

By: _____

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